DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 3, 2000, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM 71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 3, 2000, the committee will hear an update on issues relating to transmissible spongiform encephalopathy and will review safety and efficacy data pertaining to a diphtheria/tetanus/acellular pertussis vaccine manufactured by Aventis Pasteur Ltd.

Procedure: On November 3, 2000, from 8:30 a.m. to 5:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 26, 2000. Oral presentations from the public will be scheduled between approximately 1:50 p.m. and 2:20 p.m., and between approximately 3:20 p.m. and 3:50 p.m. on November 3, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 26, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 3, 2000, from 8 a.m. to 8:20 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information. (5 U.S.C. 552b(c)(4)). This portion will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications.

FDA regrets that it was unable to publish this notice 15 days prior to the November 3, 2000, meeting of the Vaccines and Related Biological Products Advisory Committee. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 17, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–27229 Filed 10–23–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3058–N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—November 7, 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee (the Committee) of the Medicare Coverage Advisory Committee (MCAC). The Committee will hear and discuss presentations from interested parties and deliberate the scientific evidence and potential clinical utility concerning FDG Positron Emission Tomography (PET). Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: The Meeting will be held on November 7, 2000, from 8 a.m. until 4 p.m., EST.

Deadline for Presentations and Comments: October 31, 2000, 5 p.m., EST.

Special Accommodations: Persons attending the meeting who are hearing-impaired and require sign language interpretation, or have a condition that requires other special assistance or accommodations, are asked to notify the Executive Secretary by October 31, 2000.

ADDRESSES: The meeting will be held at the Baltimore Convention Center, One West Pratt Street, Baltimore, Maryland 21201.

Presentations and Comments: Submit formal presentations and written comments to Constance A. Conrad, Executive Secretary, Office of Clinical Standards and Quality, Health Care Financing Administration, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at www.hcfa.gov/quality/8b.htm.

Hotline: You may access up-to-date information on this meeting on the HCFA Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Constance A. Conrad, Executive Secretary, 410–786–4631.

SUPPLEMENTARY INFORMATION: On April 27, 1999, we published a notice in the **Federal Register** (64 FR 22619) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to HCFA regarding clinical issues.

In that notice, we announced that we would generally give at least 30 days advance notice of MCAC public meetings. We also stated that persons wishing to make presentations should submit the presentations to us at least 20 days before the meeting. We now realize that this could create a problem if we shorten the 30-day notice for the meeting. In some instances, there may be less than 20 days before the meeting, making it impossible to afford the public that amount of time to submit materials. Finally, it has also been our practice to afford the public an additional period of up to 20 days following an MCAC meeting to submit any further comments they may have. Experience has shown that there will be instances when public interest in prompt consideration of an issue outweighs the 30-day advance notice, the 20-day pre-meeting deadline for presentation materials, and the 20-day